

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

To:

see form PCT/ISA/220

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/EP2007/063347

International filing date (day/month/year)
05.12.2007

Priority date (day/month/year)
06.12.2006

International Patent Classification (IPC) or both national classification and IPC
INV. A61F2/90

Applicant
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1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



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Date of completion of
this opinion

see form
PCT/ISA/210

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	<u>1-14</u>
	No: Claims	
Inventive step (IS)	Yes: Claims	<u>1-14</u>
	No: Claims	
Industrial applicability (IA)	Yes: Claims	<u>1-14</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V.

- 1 Reference is made to the following document:
D1 : EP 1 488 763 A (ENDOTEX INTERVENTIONAL SYS INC [US]) 22 December 2004 (2004-12-22)
- 2 Document D1, which is considered to represent the most relevant state of the art, discloses (the references in parentheses applying to this document):

A stenting ring made of a tube that has a characteristic wall thickness the ring defining a lumen and being equipped with at least one marker (20) made of a material different from that of the ring (col. 4, lines 15-18), the ring being expansible from a radially compact disposition with a relatively small circumference to a radially expanded disposition with a relatively large circumference, the ring exhibiting in the compact disposition a serpentine arrangement of succeeding struts (12) lying in alternate opposite directions to the longitudinal axis of the lumen *whereby*

the marker (20) has a thickness in the radial direction of the ring that is less than the characteristic wall thickness (figures 4, 5: the middle crimped part (21) of the marker has a radial thickness smaller than the strut 12; column 4, lines 46-58) and has a width that extends circumferentially around an arc of the ring (figures 4, 5);

the marker (20) is attached to the ring at a zone located at a point intermediate in the extent of said arc (§21, figures 4, 5);

the marker overlaps with a respective one of said struts (figures 4, 5).

From this, the subject-matter of independent claim 1 differs in that at each end of the ring's circumferential arc, when the ring is in the compact disposition, the respective struts moving away from each other, and from the marker, when the ring expands towards said radially expanded disposition.

The subject-matter of claim 1 is therefore novel (Article 33(2) PCT).

- 2.1 The problem to be solved by the present invention may be regarded as to achieve a high stent flexibility and stenting force (see description page 3, §2-3).

2.2 The solution to this problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT) for the following reasons:

None of the cited documents in the search report discloses markers that overlap in width the corresponding struts which move away from each other when expanded. It would not be possible to modify the marker in D1 which is crimped between the struts and locks the struts in place to such an extent as to release the corresponding struts.

2.3 Claims 2-14 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

Re Item VII.

1. Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
3. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

Re Item VIII.

1. In claims 5 - 7 "the marker" is missing which is attached to the ring (Article 6 PCT).
2. In claim 9 the "other nodes" have not been introduced before. Claim 8, to which claim

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9 has a back reference, only refers to one node (Article 6 PCT).

3. Claims 13 and 14 claim a stent as claimed in claims 8 and 9, respectively. However, claims 1-12 claim a ring and not a stent (Article 6 PCT).